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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

October 10, 2002

VIA FEDERAL EXPRESS

Sidney R. Tatum, Owner
Manns Harbor Fisheries
8505 Shipyard Road
P.O. Box 148
Manns Harbor, NC 27953

Warning Letter
03-ATL-2

Dear Mr. Tatum:

On July 29 and August 1, 2002, an investigator from the Food and Drug Administration (FDA), James P. Lewis, conducted an inspection of your seafood repacking facility located at Manns Harbor, North Carolina. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh, histamine-susceptible fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The HACCP deviations of concern are as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fresh, histamine-susceptible fish lists a critical limit at the receiving critical control point (CCP) that is not adequate to control the histamine formation hazard. Specifically, the critical limit at the receiving CCP should address the conditions (i.e. addition of ice, temperature control used, time elapsed since capture) affecting the fish while at the harvest vessel and while in transit to the processor's facility. This critical limit should also specify an acceptable temperature for the incoming fish, which if exceeded would trigger a corrective action. In addition, the receiving CCP can include other checks, such as an organoleptic examination for decomposition that can serve to ensure the fish was not subject to temperature/time abuse while in the harvest vessel and/or in transit, which could have resulted in histamine production. With regard to the critical limit at the "cooling" (storage) CCP, FDA considers that a cooler temperature of 45°F is not adequate to prevent histamine formation if the ice covering the fish has melted. Therefore, if your firm is going to rely solely on a cooler temperature as the critical limit, then it must be

modified to 40°F or below. A copy of Chapter 7 of the *Fish & Fisheries Products Hazards & Controls Guidance (Third Edition)*, titled "Scombrotoxin (Histamine) Formation" is enclosed for your information. It contains guidance on how to improve your HACCP plan for histamine-susceptible fish.

2. You must implement a record keeping system that documents the monitoring of the critical control points, in order to comply with 21 CFR 123.6(b). However, there were no monitoring records available documenting any monitoring conducted by your firm when receiving histamine-susceptible fish. In addition, your monitoring records for the "cooling" (storage) CCP fail to document the adequacy of the ice covering histamine-susceptible fish.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Barbara A. Wood, Acting Director
Atlanta District

Enclosure